REMARKS

Claims 1, 2, 4-7, 11, 12 and 14-18 are pending in the instant application. Claims 1, 2 and 4-7 have been canceled by Applicants without prejudice. Claims 11, 12 and 14-18 have been rejected. Claims 11 and 14 have been amended. Claim 18 has been canceled. New claims 19 and 20 have been added. No new matter is added by these amendments. Reconsideration is respectfully requested in light of these amendments and the following remarks.

I. Finality of Restriction Requirement

In light of the finality of the Restriction Requirement, Applicants have canceled non-elected claims 1, 2 and 4-7 without prejudice. Applicants reserve the right to file a divisional application to the canceled subject matter.

II. Rejection of Claims 11, 12 and 14-18 under 35 U.S.C. 112, first paragraph - Written Description

Claims 11, 12 and 14-18 have been rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The Examiner suggests that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the

time the application was filed, had possession of the claimed invention. Specifically, the Examiner suggests that the linear peptides contemplated by the specification are capable of being bound by MHC molecules and are of 15 amino acids in length. Accordingly, Applicants have added new dependent claims 19 and 20.

However, Applicants respectfully traverse this rejection as it pertains to rejected claims 11, 12 and 14-18.

The courts have described the essential question to be addressed in a written description requirement issue in a variety of ways. An objective standard for determining compliance with the written description requirement is, "does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed." *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989). Under *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). To satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed. The

test for sufficiency of support in a parent application is whether the disclosure of the application relied upon "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter." *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed. Cir. 1985) (quoting *In re Kaslow*, 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (Fed. Cir. 1983)). MPEP 2163 and the case law also state that if a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing even if every nuance of the claims is not explicitly described in the specification, then the adequate description requirement is met. See e.g. Vas-Cath, 935 F.2d at 1563, 19USPQ2d at 1116; Martin v. Johnson, 454 F.2d 746, 751, 172 USPQ 391, 395 (CCPA 1972)(stating "the description need not be in *ipsis verbis* [i.e., "in the same words"] to be sufficient").

Applicants respectfully disagree with the Examiner's suggestion that "direction to any length or range of lengths disclosed in the specification excepting the 15 amino acid length..." has not been provided. Applicants have shown in the instant specification how to carry out the experiments to specify the desired length, and indeed shown that loss of

certain residues causes loss of effect. Further, the requirement for critical contact residues is well known in the art among MHC class II experts [e.g. Dr. Peakman]. The mere fact that the specific examples experimented with in the instant specification are 15-mer in length in no way indicates that the specification does not reasonably convey to the skilled artisan peptide fragments of alternative lengths, for example, 14-mer or 13-mer peptide fragments.

The Examiner further suggests that Dr. Peakman's Declaration submitted with the last response on August 2, 2010 supports the Examiner's suggestion that "there is a large amount of unpredictability concerning activity of different length peptides, and there is no direction to any length or range of lengths disclosed in the specification excepting the 15 amino acid length limitation."

Applicants respectfully disagree.

The Examiner relies upon a statement in Dr. Peakman's declaration that says "it is well known in the field that the nature and length of N- and C- terminal flanking regions of a peptide can have...." while ignoring the preceding point made by Dr. Peakman that it is "simply a matter of routine experiments to identify further useful peptides. . . as set out in the patent application." Dr. Peakman's statement regarding experimentation being routine to

identify further useful peptides as set out in the patent application makes clear his understanding as a skilled artisan that the inventors were in possession of the claimed invention at the time of filing despite that fact that every nuance of the claims is not explicitly described in the specification. Accordingly, adequate description requirement is met for the instant claimed invention.

Claims 11, 12, 14, 15, 17 and 18 have been further rejected under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement as the Examiner suggests that the claims are drawn to a broad genus of immunologically effective linear peptide fragments of a human platelet antigen while the specification discloses the specific peptides consisting of SEQ ID NOs 1-30.

Applicants respectfully traverse this rejection.

In a recent decision from the Court of Appeals for the Federal Circuit, *Falkner v. Inglis*, 448 F.3d 1357, 1366, 79 USPQ2d 1001, 1007 (Fed. Cir. 2006), the Federal Circuit explained that, "(1) examples are not necessary to support the adequacy of a written description; (2) the written description standard may be met ... even where actual reduction to practice of an invention is absent; and (3) there is no per se rule that an adequate written description of an invention that involves a biological macromolecule

must contain a recitation of known structure." Also see *Capon v. Eshhar*, 418 F.3d 1349, 1357, 76 USPQ2d 1078, 1085 (Fed. Cir. 2005) wherein the Court state that "The 'written description' requirement must be applied in the context of the particular invention and the state of the knowledge... As each field evolves, the balance also evolves between what is known and what is added by each inventive contribution." Also see MPEP 2163.

The Examiner has acknowledged that the specification teaches 30 specific peptides. This large number of working examples, when the Federal Circuit has recently acknowledged that working examples are not necessary to support the adequacy of a written description, clearly supports the genus of linear peptide fragments claimed.

Withdrawal of these rejections under 35 U.S.C. 112, first paragraph, for lack of written description, is respectfully requested.

III. Rejection of Claims 11, 12 and 14-17 under 35 U.S.C. 112, first paragraph - Lack of Enablement

The rejection of claims 11, 12 and 14-17 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, has been maintained.

Applicants respectfully traverse this rejection.

At the outset, it is respectfully pointed out that claim 11 has been amended to recite a method for managing or reducing the likelihood of a condition caused by exposure to an antithetical allele of a platelet by transfusion or during pregnancy, thus rendering moot the Examiner's concerns regarding the term prevention. Support for this amendment is provided in the specification at, for example, page 4.

Further, in an earnest effort to advance the prosecution of this case and to address the Examiner's comment that no working examples in animal models have been provided, Applicants is submitting herewith in vivo data originally presented in corresponding European Patent Application No. 04743254.7 confirming effective induction of T-cell proliferation in mice. In this respect, the data presented herewith confirms that non-invasive nasal administration of an immunologically effective peptide fragment expands a regulatory T-cell population in the draining lymph nodes of humanized mice. This data is consistent with the assertion that the peptides claimed have immunomodulatory effects in vivo that can be exploited therapeutically.

Specifically, Figure 1 of the enclosed in vivo data shows the analysis of CD4+ cells bearing the regulatory T-

cell marker FoxP3. An increase in FoxP3+ CD4+ T-cells is clearly seen in mice nasally dosed with peptide in comparison to control mice with no treatment. This increase is consistent with induction of specific regulatory T-cells by peptide and therefore provides evidence that the immunologically effective peptides successfully and effectively induce T-cell proliferation in vivo and thus can be used to tolerize subjects who have been exposed to an antithetical allele of a platelet by transfusion or during pregnancy as claimed.

Withdrawal of this enablement rejection under 35 U.S.C. 112, first paragraph, is therefore respectfully requested.

IV. Rejection of Claims 11, 12, 14, 15, 17 and 18 under 35 U.S.C. 112, second paragraph

Claims 11, 12, 14, 15, 17 and 18 have been rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner suggests that the term "immunologically effective" is a relative term which renders the claims indefinite. Further, claims 14-16 are suggested to be indefinite as being dependent from canceled claim 13.

Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have amended claim 11 to delete the phrase "immunologically effective", reciting instead "administering to a patient a linear peptide fragment of a human platelet antigen (HPA) recognized by T-cells." Support for this amendment is provided in the specification at, for example, pages 7-8.

Further, Applicants have amended claim 14 to depend from claim 11.

Withdrawal of these rejections is respectfully requested.

V. Rejection of Claim 18 under 35 U.S.C. 102(b)

Claim 18 has been rejected under 35 U.S.C. 102(b) as being anticipated by Flug et al.

It is respectfully pointed out that claim 18 has been canceled, thus rendering moot this rejection.

Withdrawal of this rejection is respectfully requested.

VI. Obviousness-type double patenting rejections

Claims 11, 12 and 14-18 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 16-22 of copending Application No. 12/096,092.

Claims 11, 12 and 14-18 also stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 14-32 of copending Application No. 12/523,549.

Applicants respectfully traverse these rejections.

MPEP §804(I)(B)(1) states "[i]f a "provisional" nonstatutory obviousness-type double patenting (ODP) rejection is the only rejection remaining in the earlier filed of the two pending applications, while the later-filed application is rejectable on other grounds, the examiner should withdraw that rejection and permit the earlier-filed application to issue as a patent without a terminal disclaimer."

Applicants believe that the amendments and arguments of this response overcome all other pending rejections.

Therefore, since the filing or 371(c) date of the instant application precedes the filing or 371(c) date for U.S. Application Serial No. 12/096,092 and U.S. Application Serial No. 12/523,549, Applicants respectfully request in accordance with MPEP §804(I)(B)(1) that the Examiner withdraw this rejection based on the later-filed application.

VII. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,

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